

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** This Justification for Other Than Full and Open Competition is prepared by the Department of Veterans Affairs Network Contracting Office 6 (NCO 6) on behalf of the Veterans Affairs Medical Center in Richmond, VA in support of Purchase Request No. 652-16-1-077-0055.
2. **Nature and/or Description of the Action Being Processed:** This procurement is for the Stryker Anchorage CP Plating System in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2. This justification provides the rationale for contracting by other than full and open competition for the Stryker Anchorage CP Plating System. A firm fixed priced purchase order will be awarded on a sole source basis to Stryker Orthopaedics (dba Howmedica-Osteonics Corporation) (DUNS: 058311945).
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Anchorage Cross Plate system is an orthopedic implant plating system used for podiatric procedures to fuse joints. The system features a unique approach that uses a diagonal, cross-joint screw to create mechanical compression. The Anchorage CP system comes in the form of a kit, including anatomically shaped plates, hardware and tools for installation. The IGE for this requirement is \$[Redacted]. Delivery will be 5 days after receipt of order (ARO).
4. **Statutory Authority Permitting Other than Full and Open Competition:** The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;

() (2) Unusual and Compelling Urgency per FAR 6.302-2;

() (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;

() (4) International Agreement per FAR 6.302-4

() (5) Authorized or Required by Statute FAR 6.302-5;

() (6) National Security per FAR 6.302-6;

() (7) Public Interest per FAR 6.302-7;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Stryker Orthopaedics (dba Howmedica-Osteonics Corporation) is the only available source to meet this requirement. The Anchorage CP Plating System differs in design from competing products in that it provides unsurpassed compression at the first metatarsal phalangeal joint specifically for patients who are both elderly, somewhat osteoporotic with low vitamin D levels, diabetics and non-compliant individuals who ambulate against medical advice. If the patient is required to be nonweightbearing from the first metatarsal phalangeal joint fusion for 8-10 weeks there will be some disuse osteoporosis which further necessitates the bi-cortical screw that is inherently designed within the

anchorage plating system. The facility has used other first metatarsal phalangeal joint fusion plating systems that do not have the bi-cortical screw incorporated into the actual plate itself and have found that when the patient ambulates prematurely, the plate fractures at the level of the joint which was originally intended to be fused. This requires removal of the plate and screws necessitating both a second surgical procedure for explantation, which sometimes negates the ability to fixate the joint sufficiently as a result of the destruction of the proximal phalanx and the first metatarsal head secondary to potential screw movement and level of plate involvement. The patient will have an increase in the amount of edema postoperatively with a less favorable outcome when the patient attempts to transition back into shoe gear. Use of the Anchorage CP Plating System will provide the patient with the most conducive outcome to allow them to transition back into their normal shoe gear, with a diminished risk for plate disruption. Stryker does not authorize distributors for any products within its orthopedics division (Stryker Orthopaedics).

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A sources sought was posted to FBO.gov on 4 November 2015. Two (2) responses confirmed that they were not capable. One small business suggested a product that is similar, but does not contain the same unique design features as the sole source product. A response was received from Stryker, formally providing product information for the Anchorage CP system.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Market Research indicates that similar orthopedic plating kits range from \$85,000 to \$200,000 per unit. Stryker is providing a [redacted] discount from list price.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted by reviewing manufacturer websites, product brochures and conducting a sources sought on FBO.gov.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** There are no other considerations other than those already stated.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Buffalo Supply, Inc.
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** For future requirements and subsequent acquisitions of this type, in order to overcome any barriers to competition, market research will be used as a guide to determine whether or not the market for competition exists. The appropriate procurement strategy will then be determined and followed.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

[Redacted]
RN, OR Surgical Services
McGuire VAMC (Richmond VAMC)

Date

13. Approvals in accordance with FAR 6.304

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[Redacted]
Contracting Officer, Supply Team 1
NCO 6

Date

[Redacted]
Quality Assurance
NCO 6

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

[Redacted]
Director of Contracting or Designee
NCO 6

Date